Eur J Vasc Endovasc Surg 16, 142–147 (1998)

Evaluation of the Risks of Using an Oversized Balloon Catheter in the Human Infrarenal Abdominal Aorta

X. Chaufour*, **G. H. White, B. D. Hambly, W. Yu, J. May, J. P. Harris and M. S. Stephen**

Endovascular Research Unit, Department of Surgery & Pathology, University of Sydney, N.S.W., Australia

Objectives: *To evaluate the effects on the aortic wall of balloon dilatation as utilised in deployment of stent-graft devices during endoluminal repair of infrarenal abdominal aortic aneurysm.*
Methods: *Large dilatation balloons were expanded within the aorta of 41 cadavers. Testing was done to evaluate the effect of differing degrees of balloon oversizing, at pressures in the range of 0.15–2.5 atm. The aorta was then opened for macroscopic inspection.*
Results: *In group 1 (mild atherosclerosis) no macroscopic abnormalities were detected with up to 6 mm oversized balloon. In group 2 (moderate atherosclerosis) fracture of atherosclerotic plaque occurred in seven of 14 aortas (50%) with 2.5 mm–4 mm oversized balloon. In group 3 (severe atherosclerosis) fracture of atherosclerotic plaque occurred in six of seven (85%) with 2.5 mm to 4 mm oversized balloon and rupture of the aorta occurred at 6 mm oversizing.*
Conclusions: *This study suggests that balloon overdilatation of the aorta by 2 mm, at pressures less than 2 atmospheres, allows safe deployment even in the presence of severe atheroma. Larger amounts of overdilatation are relatively safe in mildly atherosclerotic aorta. Aortic rupture is unlikely with overdilatation up to 6 mm, especially in less calcified vessels.*

Key Words: Balloon catheter; Human aorta; Endoluminal repair.

Introduction

The feasibility of endoluminal repair of abdominal aortic aneurysms has been adequately demonstrated during the last 5 years, with encouraging early follow-up. Stent-graft devices currently used for endoluminal exclusion procedures fall into two main groups (i) self-expanding[1–4] and (ii) balloon expandable.[5–7] The use of large balloon catheters for deployment of balloon-deployed devices, or for modelling self-expandable devices, however, has raised the possibility of aortic trauma. Cases of aortic rupture in the region of the proximal neck of the aneurysm have been reported during the deployment of both balloon-expandable[8,9] and self expanding devices.[10]

The aim of this study was to evaluate the potential for aortic damage during endoluminal stent-graft deployment with particular reference to the problems posed by using an oversized balloon. The risk of using an oversized balloon must also take into consideration the difficulty of determining the true luminal diameter of the aorta from aortography and computed tomography (CT). A discrepancy of 1–5 mm may be observed between these two modalities when aortic diameter is measured with a calibrated catheter,[11] with CT generally giving the larger estimate.

The two parameters inducing tension in the arterial wall during balloon dilatation are inflation pressure and balloon diameter. While the inflation pressure is an easily controllable parameter, the diameter of the balloon catheter has to be chosen after determination of the lumen of the infrarenal aorta using CT and aortography, and the potential for error must be taken into account.

The circumferential force in the wall of an artery is called hoop stress and may be approximated by Laplace's law where: Hoop Stress = pressure × diameter. The wall tension resulting from outward fluid pressure is proportional to both pressure and diameter[12] and as a result a larger balloon has more dilating power. For example, the tension in the wall of an artery developed by a 20 mm balloon at 2 atm is equivalent to the tension developed by a 5 mm balloon at 8 atm. Since rupture of the vessel may occur if the balloon is oversized, previous work was carried out to determine the true diameter of commercially available large angioplasty balloons; this demonstrated

* Please address all correspondence to: X. Chaufour, Endovascular Research Unit, Department of Surgery, Blackburn Building DO6, University of Sydney, NSW 2006, Australia.

1078–5884/98/080142 + 06 $12.00/0

Table 1. Calliper measurements of balloon diameter at different pressures compared to nominal diameter.

Nominal diameter	1.0 atm	2.0 atm	2.5 atm	3.0 atm	4.0 atm
18 mm	17.2 mm	17.4 mm	17.6 mm	17.8 mm	18.1 mm
20 mm	18.1 mm	18.2 mm	18.6 mm	19.3 mm	19.7 mm
	18.1 mm	18.2 mm	18.6 mm	18.9 mm	19.3 mm
23 mm	21.1 mm	21.4 mm	22.3 mm	22.6 mm	22.8 mm
	21.1 mm	21.2 mm	22.3 mm	22.6 mm	23.0 mm
	21.3 mm	21.5 mm	22.4 mm	22.8 mm	23.4 mm
25 mm	22.1 mm	22.4 mm	23.1 mm	23.7 mm	24.3 mm
	22.4 mm	22.6 mm	23.2 mm	23.5 mm	24.3 mm

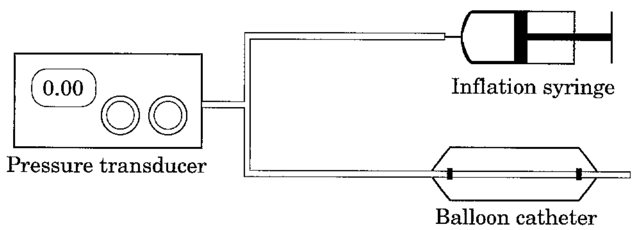

Fig. 1. The balloon catheter is inflated with an inflation syringe connected to a pressure transducer.

that the diameter of these balloons varied at different inflation pressures.[13]

Materials

Studies were carried out during 41 autopsies (27 male, 14 female; age 18–93, mean 58.4). Time of death before autopsy was performed ranged from 4 to 56 h with a mean of 26 h.

Large diameter Omega NV balloon dilatation catheters (William A. Cook Australia PTY. Ltd) with diameters ranging from 15–25 mm were used (the same balloon catheters have been used in our clinical practice of endoluminal repair of AAA[9,11]). The diameter of each balloon had been previously measured over the pressure range 1–4 atmospheres, so that the true diameter was known for the purpose of analysis (Table 1).

Balloons were inflated with water using an inflation syringe (Merit Medical Systems) connected to a pressure transducer (DPI 700, Druck Limited, +/− 0.15% F.S accuracy). The balloon catheter and the inflation syringe were connected to the pressure transducer by pressure tubing filled with water; measurements were made after removing all air bubbles from the tubing system (Fig. 1).

Methods

All organs were removed in one block from the tongue to the rectum according to the technique of Letulle.[14,15] The excised monobloc was then positioned with the aorta lying superficially. All periaortic tissue was left intact apart from the lumbar arteries, which were divided.

Minor dissection of the aorta was performed over a segment of 5 cm distal to the renal arteries. The adventitia was freed of all surrounding tissue, allowing accurate measurement of the aortic diameter. The external diameter of the infrarenal aorta was measured by calliper measurement. Initial pilot studies showed that the true diameter of the lumen of the aorta at normal blood pressure was slightly larger than the external diameter, without blood pressure, in the cadavre.

Each specimen was tested by overdilatation with a single balloon, with measurements of the aortic diameter done at a series of inflation pressures up to 2.5 atm, unless rupture of the aorta occurred before that point. A balloon catheter with balloon diameter in the range of 1–9 mm larger than the external aortic diameter was selected and was introduced into the abdominal aorta through the descending thoracic aorta after opening the aortic arch. The balloon catheter was therefore of a size calculated to provide overdilatation of the infrarenal segment and was positioned immediately below the level of the renal arteries. The aorta was initially expanded to physiological systolic pressure (0.15 atm or 110 mmHg) in order to calculate the external diameter of the aorta at normal blood pressure. In each specimen, these external measurements were made at a point 3 cm below the renal arteries using a Vernier calliper (Mitutoyo, Japan).

Measurements of the external aortic diameter were next made at increasing increments of pressure within the balloon (0.15, 0.30, 0.60, 1, 1.5, 2 and 2.5 atm). Stabilised pressure measurements were made after 60 s of inflation, with balloon positioning checked at each step of the inflation.

After completion of measurements the aorta was opened from the aortic arch to the bifurcation. Macroscopic aspects of the pathology of the aortic wall were classified into three groups according to the degree of

Table 2. Aortic measurements for group 1 (mild disease) showing balloon size used and amount of oversizing.

Group 1	Mild disease													
Case number	13	21	19	41	32	30	14	28	25	1	9	3	2	4
Balloon size (mm)	18.6	18.6	18.6	22.3	18.6	18.6	18.6	18.6	22.3	23.1	22.6	22.4	23.1	23.1
Lumen size (mm)	16.7	15.9	15.7	19.4	15.5	15.1	14.7	14.5	16.9	18.0	16.0	15.7	16.0	14.9
Oversizing (mm)	1.9	2.7	2.9	2.9	3.1	3.5	3.9	4.1	5.4	6.1	6.6	6.7	7.1	8.1
Aortic diameter at 0.15 atm	19.7	18.9	18.7	22.4	18.5	18.1	17.7	17.5	19.9	20.0	19.0	18.7	19.0	17.9
Aortic diameter at 0.30 atm	20.3	19.4	19.0	22.9	18.9	18.5	18.2	18.4	20.6	20.6	19.4	19.1	19.2	18.4
Aortic diameter at 0.60 atm	20.4	19.7	19.6	23.1	19.2	19.6	19.1	19.2	21.3	21.5	19.9	19.6	19.6	18.7
Aortic diameter at 1.0 atm	20.5	19.9	20.0	23.3	19.3	19.7	19.5	19.2	21.7	22.3	20.3	20.0	20.0	19.2
Aortic diameter at 1.5 atm	20.6	20.0	20.5	23.5	19.4	19.8	20.0	19.3	22.3	22.9	21.4	20.6	21.5	19.7
Aortic diameter at 2.0 atm	20.8	20.0	20.7	23.5	19.5	19.8	20.2	19.3	22.8	23.6	21.8	23.3	21.9	20.3
Aortic diameter at 2.5 atm	21.0	20.4	20.8	23.7	19.7	19.8	20.3	19.4	23.3	24.0	23.4		22.3	20.7
Aortic diameter at 3.0 atm													24.5	24.3

calcification and severity of atheroma as mild atherosclerosis (<30%), moderate atherosclerosis (30–60%), and severe atherosclerosis (>60%). Damage was classified as: (i) no macroscopic abnormalities, (ii) dissection of the intima and the media, (iii) fracture of atherosclerotic plaque with intact adventitia, and (iv) rupture of the adventitia. These macroscopic findings were confirmed by histological examination after haematoxylin and eosin staining, elastin studies (Verhoeff Von Gieson staining) and Masson's Trichrome staining for collagen and muscle.

The true diameter of the lumen of the treated aorta was calculated by subtracting the thickness of the aortic wall ($\times 2$) from the measurement of the external diameter of the infrarenal aorta at physiological pressure. The thickness of the aortic wall varied between 1.5–3 mm depending on the degree of vascular disease.[16] The precise amount of balloon overdilatation that had been applied was then calculated as the difference between true aortic lumen and balloon diameters.

Results

Results for the 41 cases were divided into three groups based upon the macroscopic degree of vascular disease. The mean age increased from group 1 (40 years) to group 3 (71 years); this is explained by the fact that the severe atherosclerotic disease seen in group 3 occurs more frequently in the aged.

Group 1. (Mild atherosclerosis; 14 cases, 11 male, three female; age range 18–65, mean 40). As shown in Table 2, the infrarenal aorta was overdilated at 2.5 atm pressure by up to 5.4 mm without obvious vessel trauma. Dissection of the media started to occur in two cases after oversizing by more than 6 mm (6.1 and 6.6 mm). Rupture of the aorta occurred in three cases, at 2 atm and 6.7 mm oversize, at 3 atm and 7.1 mm oversize and at 3 atm with a 8.1 mm oversize.

Group 2. (Moderate atherosclerosis; 18 cases, nine male, nine female; age range 51–93, mean 66.5). In seven cases, with a range of balloon oversize from 2.3–3.9 mm, there were no traumatic changes noted in the aortic wall (Table 3). Fracture of atherosclerotic plaque occurred in seven cases, with a range of balloon oversize from 2.4–4.7 mm. Rupture of the adventitia occurred in four cases, at 1.5 atm with a 6.7 m oversize, 2.5 atm with a 7.1 mm oversize, 3 atm with a 7.1 atm oversize and 2.5 atm with a 8.5 mm oversize.

Group 3. (Severe atherosclerosis; nine cases, seven male, two female; age range 63–87, mean 71). No obvious trauma was seen in two cases oversized by 1.5 mm and 2.5 mm, but fracture of atherosclerotic plaque occurred in six cases with a range of oversize from 2.5 mm to 4.3 mm and rupture of the aorta occurred at 2.5 atm with 6 mm oversize in one case (Table 4).

The outcome of overdilatation for each case, according to the severity of mural disruption after balloon dilatation, is shown diagrammatically in Fig. 2.

Discussion

There are no studies to date which have considered the risk of using oversized balloon catheters in the aorta during deployment of an endoluminal stent-graft, but reports of aortic rupture during these procedures suggest that it is an important factor which should be taken into account. The aim of overdilation of the aorta in this study was therefore to provide guidance to the safety limits and risks of overdilating the aorta during balloon-deployed endovascular grafting, and to observe the effects of such overdilatation

Table 3. Aortic measurement for group 2 (moderate disease) showing balloon size used and amount of oversizing.

Group 2	Moderate disease																	
Case number	15	35	38	26	34	5	29	33	18	23	24	27	22	16	6	8	10	7
Balloon size (mm)	18.6	18.6	18.6	18.6	18.6	23.1	21.4	21.4	18.6	22.4	18.6	22.3	22.3	18.6	22.4	23.1	23.7	23.1
Lumen size (mm)	16.3	16.2	16.1	15.8	15.8	20.0	17.9	17.8	15.0	18.7	14.7	18.2	18.1	13.9	15.7	15.7	15.7	13.9
Oversizing (mm)	2.3	2.4	2.5	2.8	2.8	3.1	3.5	3.6	3.6	3.7	3.9	4.1	4.2	4.7	6.7	7.1	8.0	8.5
Aortic dilatation at 0.15 atm	20.7	20.9	19.1	19.9	18.8	25.1	21.9	19.8	19.8	22.6	17.7	21.4	21.1	17.1	18.9	19.0	18.7	17.8
Aortic dilatation at 0.30 atm	20.9	21.3	19.5	20.3	19.1	26.3	22.5	21.2	20.3	23.2	18.0	21.8	21.5	17.6	19.8	19.5	19.1	18.4
Aortic dilatation at 0.60 atm	21.1	21.7	19.8	20.6	19.5	26.6	22.9	21.7	20.8	23.6	18.3	22.6	22.1	18.1	20.5	19.7	19.6	18.9
Aortic dilatation at 1.0 atm	21.5	22.0	20.0	21.2	19.9	26.8	23.4	22.4	21.4	24.1	18.8	23.1	22.5	18.5	21.4	20.3	19.8	19.2
Aortic dilatation at 1.5 atm	21.8	22.2	20.0	21.2	20.0	27.1	23.8	22.8	21.9	24.8	19.4	23.6	23.3	20.1	23.7	21.4	20.0	19.8
Aortic dilatation at 2.0 atm	21.8	22.3	20.0	21.4	20.0	27.2	24.0	23.0	22.1	25.1	20.0	23.9	23.8	20.5	24.6	21.6	20.4	20.9
Aortic dilatation at 2.5 atm	21.8	22.3	20.1	21.5	20.1	27.2	24.0	23.1	22.4	25.3	20.3	24.5	24.1	20.8		23.7	21.6	23.2
Aortic dilatation at 3.0 atm																	23.4	

Table 4. Aortic measurements for group 3 (severe disease) showing balloon size used and amount of oversizing.

Group 3	Severe disease								
Case number	39	40	37	36	17	20	12	31	11
Balloon size (mm)	18.6	17.6	18.6	18.6	18.6	18.6	23.1	21.1	22.1
Lumen size (mm)	17.1	15.1	16.1	16.0	15.2	15.2	19.0	16.8	16.1
Oversizing (mm)	1.5	2.5	2.5	2.6	3.4	3.4	4.1	4.3	6.0
Aortic diameter at 0.15 atm	21.7	18.5	19.1	19.0	19.0	19.8	23.4	20.8	20.1
Aortic diameter at 0.30 atm	21.9	18.7	19.2	19.5	19.6	20.4	24.2	21.0	20.2
Aortic diameter at 0.60 atm	22.2	19.0	19.6	20.1	20.1	20.7	24.9	21.4	20.9
Aortic diameter at 1.0 atm	22.5	19.3	20.0	20.3	20.8	21.0	25.3	21.8	23.5
Aortic diameter at 1.5 atm	22.8	19.6	20.4	20.3	21.3	21.5	25.8	23.7	
Aortic diameter at 2.0 atm	23.0	19.9	20.4	20.4	21.4	21.8	26.0		
Aortic diameter at 2.5 atm	23.2	20.0	20.6	20.5	21.4	22.2	26.0		

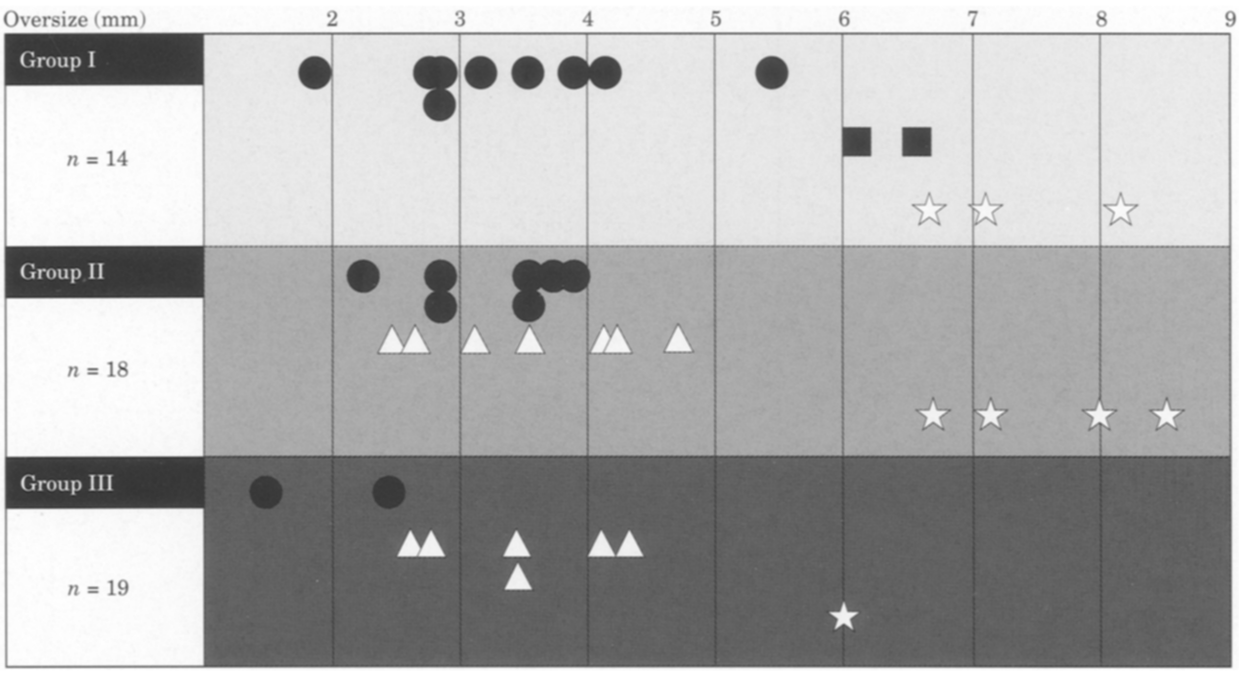

Fig. 2. This graph summarises the macroscopic results of the three groups, graded from 1 to 3 based upon the degree of vascular disease. The outcome of overdilatation for each case were coded according to the severity of mural disruption after balloon dilatation. (○) No macroscopic abnormalities; (△) fracture of atherosclerotic plaque, adventitia intact; (□) dissection of intima and media; (◇) rupture of aorta.

on the aortic wall. The size increments of the aortic wall when overdilating with a large balloon are related to pressure, since the two parameters inducing tension in the arterial wall during balloon dilatation are inflation pressure and balloon diameter.

A major problem faced in the design of this study was that the resting diameter of the aorta in the cadaver did not necessarily match that in the living state due to possibility of decreased diameter without normal blood pressure. We corrected for this by measuring the external diameter of the aorta at physiological pressures, and subtracting the wall thickness to derive the luminal diameter. Direct calliper measurements of the lumen were not possible, since the aorta could not be opened prior to balloon treatment, and radiological contrast study was considered impractical due to the post-mortem diameter reduction and the lack of adequate X-ray equipment in the morgue area.

In this study, adventitial rupture occurred in all groups when the aortic lumen was overdilatated by more than 6 mm. During deployment of an endoluminal graft it is undesirable to fracture an atherosclerotic plaque or create a dissection of the media. The aim is to obtain secure device attachment with no endoleak[17] and therefore a compromise between attachment and over dilatation must be found.

This study clearly shows that there is a progressively reduced safety margin with overdilatation and with increasing arterial disease, the risk of atherosclerotic plaque fracture being greater when the infrarenal aorta is severely diseased. Using an inflation pressure of 2.5 atm, the absolute limit of safe deployment for balloon oversizing was 2 mm in group 3 (severe atherosclerosis) compared to 3 mm in group 2 (moderate atherosclerosis) and 5 mm in group 1 (minor atherosclerosis). Of particular importance was the fact that rupture occurred before generation of 2 atm where balloon oversizing was greater than 6 mm in a heavily calcified aorta (Table 4).

In the clinical setting, the presence of the endovascular graft between the balloon and the aortic wall may provide significant protection against the damage inflicted by the balloon. Nevertheless, it is common for part of the balloon to extend above or below the margins of the stent-graft so that part of the aortic wall may not be protected. In addition, any information regarding the dangers of balloon inflation within the aorta stills bears some clinical relevance to the practice of adjunctive dilatation within a stent-graft during its deployment. This study therefore establishes a baseline against which the true protective influences of a stent outside the balloon can be tested. This will be done in further experiments.

The study was carried out on post-mortem specimens because human aortic medial structure has unique properties when compared with other mammals. Wolinsky *et al.* showed that the human abdominal aorta has fewer lamellar units than would be predicted for its diameter than other species and the infrarenal aorta has fewer of these units than the rest of the aorta.[18] With only 28 lamellar units, human abdominal aorta media had non-demonstrable vasa vasorum despite this relatively great thickness.[19] The medial thickness of the human aorta seems appropriate for its diameter, but its totally avascular media is thicker than that of the avascular zones of aorta of species with medial vasa vasorum. This structural specificity prompted us to use human cadaveric aortas as our model, although we acknowledge that factors such as shrinkage due to the absence of blood pressure, lack of muscle tone and autolytic changes should be taken into account when interpreting our results.[20]

This study has established some general guidelines applicable to the safety of inflation of large diameter balloons during the deployment of endoluminal devices within the human aorta. Specifically it would seem that overdilatation of the aorta by 2 mm at pressures under 2 atm allows safe deployment even in the presence of severe atheroma, and that rupture of the aorta is unlikely with overdilatation up to 6 mm, especially in less calcified vessels.

References

1 Moore WS, Rutherford RB. Transfemoral endovascular repair of abdominal aortic aneurysms. Results of the North American EVT phase 1 trial. *J Vasc Surg 23;* **4**: 543–553.

2 Blum U, Langer M, Spillner G, Mialhe C *et al.* Abdominal aortic aneurysms: preliminary technical results with trans femoral placement of endovascular self expanding stent-grafts. *Radiology* 1996; **198**: 25–31.

3 Dake M, Miller DC, Semba CP, Mitchell RS, Walker PJ, Liddell RP. Transluminal placement of endovascular stented grafts for the treatment of descending thoracic aortic aneurysms. *New Eng J Med* 1994; **331**: 1729–1734.

4 Chuter TAM, Green RM, Ouriel K, Fiore W, DeWeese JA. Transfemoral endovascular aortic graft placement. *J Vasc Surg* 1993; **18**: 185–197.

5 Parodi JC, Palmaz JC, Barone HD. Transfemoral intraluminal graft implantation for abdominal aortic aneurysms. *Ann Vasc Surg* 1991; **5**: 491–499.

6 White GH, Yu W, May J, Stephen MS, Waugh RC. A new non-stented balloon-expandable graft for straight or bifurcated endoluminal bypass. *J Endovasc Surg* 1994; **1**: 16–24.

7 Veith FJ. Transluminally placed endovascular stented grafts and their impact on vascular surgery. *Ann Surg* 1994; **20**: 855–856.

8 Bergeron P, Chambran P, Fiorani B, Zheng J, Amichot A. Endo-aortic repair: risks and prevention. *J Endovasc Surg* 1998, February.

9 White GH, Yu W, May J, Waugh RC, Chaufour X, Stephen MS. Three-year experience with the White–Yu endovascular GAD graft in aortic and iliac aneurysms. *J Endovasc Surg* 1997; **4**: 124–136.

10 Personal communication: Dr Mark Fillinger at the International Endovascular Symposium, Dec 1996.

11 White GH, May J, Yu W. Stented and non-stented grafts for endoluminal repair of abdominal aortic aneurysms. In: Donayre C, Chuter T, White R, eds. *Endoluminal Vascular Prostheses.* Boston, Little, Brown & Company, 1994: 107–152.

12 Lawrence A, Yeatman J. Angioplasty balloons, guidewires and other equipment: principles, design and selection. In: Anh SS, Moore W, eds. *Endovascular Surgery.* Philadelphia: W.B. Saunders Company, 1992: 154–165.

13 Chaufour X, White GH, Yu W, May J, Stephen MS. Diameter of large balloons used in endoluminal graft deployment values with inflation pressure. *J Endovasc Surg* 1998; in press.

14 Trump BF, Jones RT, Mergner WJ. Principles of autopsy techniques. In: Ludwig J, ed. *Current Methods of Autopsy Practice.* Philadelphia: W.B. Saunders Company, 1979: 3–7.

15 Baker RD. *Post-mortem Examination: Specific Methods and Procedures.* Philadelphia: W.B. Saunders Company, 1967.

16 Bloom W, Fawcett DW. Blood vascular system. In: Bloom W, Fawcett DW, eds. *A Textbook of Histology.* Philadelphia: W.B. Saunders Company, 196: 358–373.

17 White GH, Yu W, May J, Chaufour X, Stephen MS. Endoleak as a complication of endoluminal grafting of abdominal aortic aneurysms: classification, diagnosis and managements. *J Endovasc Surg* 1997; **4**: 152–168.

18 Wolinsky H, Glagov S. A lamellar unit of aortic medial structure and function in mammals. *Circulation Research* 1967; **20**: 99–111.

19 Wolinsky H, Glagov S. Comparison of abdominal and thoracic aortic medial structure in mammals. Deviation of man from the usual pattern. *Circulation Research* 1969; **25**: 677–686.

20 Zolliker CL, Ferral H, Cragg AH, Castaneda-Zuniga WR, Amplatz K. Mechanism of transmural angioplasty. In: Castaneda-Zuniga WR, Tadavarthy SM, eds. *Interventional Radiology.* Baltimore: Williams & Wilkins, 1992; **19**: 319–370.

Accepted 24 March 1998